

CIPRO- ciprofloxacin hcl 500mg tablet, film coated
Advanced Rx Pharmacy of Tennessee, LLC

Ciprofloxacin HCl 500mg tablets #30

Medication Guide Section

MEDICATION GUIDE

Ciprofloxacin Tablets, USP for oral use (sip" roe flox' a sin)

Read this Medication Guide before you start taking ciprofloxacin tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about ciprofloxacin tablets?

Ciprofloxacin tablets, a fluoroquinolone antibacterial medicine, can cause serious side effects. Some of these serious side effects can happen at the same time and could result in death.

If you get any of the following serious side effects while you take ciprofloxacin tablets, you should stop taking ciprofloxacin tablets immediately and get medical help right away.

1. Tendon rupture or swelling of the tendon (tendinitis).

Tendon problems can happen in people of all ages who take ciprofloxacin tablets. Tendons are tough cords of tissue that connect muscles to bones. Symptoms of tendon problems may include:

pain

swelling

tears and swelling of the tendons including the back of the ankle (Achilles), shoulder, hand, thumb, or other tendon sites.

The risk of getting tendon problems while you take ciprofloxacin tablets is higher if you:

are over 60 years of age

are taking steroids (corticosteroids)

have had a kidney, heart or lung transplant.

Tendon problems can happen in people who do not have the above risk factors when they take ciprofloxacin tablets.

Other reasons that can increase your risk of tendon problems can include:

physical activity or exercise

kidney failure

tendon problems in the past, such as in people with rheumatoid arthritis (RA).

Stop taking ciprofloxacin tablets immediately and get medical help right away at the first sign of tendon pain, swelling or inflammation. The most common area of pain and swelling is the Achilles tendon at the back of your ankle. This can also happen with other tendons.

Tendon rupture can happen while you are taking or after you have finished taking ciprofloxacin tablets. Tendon ruptures can happen within hours or days of taking ciprofloxacin tablets and have happened up to several months after people have finished taking their fluoroquinolone.

Stop taking ciprofloxacin tablets immediately and get medical help right away if you get any of the following signs or symptoms of a tendon rupture:

- hear or feel a snap or pop in a tendon area
- bruising right after an injury in a tendon area
- unable to move the affected area or bear weight

The tendon problems may be permanent.

2. Changes in sensation and possible nerve damage (Peripheral Neuropathy). Damage to the nerves in arms, hands, legs, or feet can happen in people who take fluoroquinolones, including ciprofloxacin tablets. Stop taking ciprofloxacin tablets immediately and talk to your healthcare provider right away if you get any of the following symptoms of peripheral neuropathy in your arms, hands, legs, or feet:

- pain
- burning
- tingling
- numbness
- weakness

Ciprofloxacin tablets may need to be stopped to prevent permanent nerve damage.

3. Central Nervous System (CNS) effects. Mental health problems and seizures have been reported in people who take fluoroquinolone antibacterial medicines, including ciprofloxacin tablets. Tell your healthcare provider if you have a history of seizures before you start taking ciprofloxacin tablets. CNS side effects may happen as soon as after taking the first dose of ciprofloxacin tablets. Stop taking ciprofloxacin tablets immediately and talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:

- seizures
- hear voices, see things, or sense things that are not there (hallucinations)
- feel restless or agitated
- tremors
- feel anxious or nervous
- confusion
- depression
- reduced awareness of surroundings
- trouble sleeping
- nightmares
- feel lightheaded or dizzy
- feel more suspicious (paranoia)
- suicidal thoughts or acts
- headaches that will not go away, with or without blurred vision
- memory problems
- false or strange thoughts or beliefs (delusions)

The CNS changes may be permanent.

4. Worsening of myasthenia gravis (a problem that causes muscle weakness).

Fluoroquinolones like ciprofloxacin tablets may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Tell your healthcare provider if you have a history of myasthenia gravis before you start taking ciprofloxacin tablets. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

What are ciprofloxacin tablets?

Ciprofloxacin tablets are a fluoroquinolone antibacterial medicine used in adults age 18 years and older to treat certain infections caused by certain germs called bacteria. These bacterial infections include:

- urinary tract infection

chronic prostate infection
lower respiratory tract infection
sinus infection
skin infection
bone and joint infection
nosocomial pneumonia
intra-abdominal infection, complicated
infectious diarrhea
typhoid (enteric) fever
cervical and urethral gonorrhea, uncomplicated
people with a low white blood cell count and a fever
inhalational anthrax
plague

Studies of ciprofloxacin tablets for use in the treatment of plague and anthrax were done in animals only, because plague and anthrax could not be studied in people.

Ciprofloxacin tablets should not be used in patients with acute exacerbation of chronic bronchitis, acute uncomplicated cystitis, and sinus infections, if there are other treatment options available.

Ciprofloxacin tablets should not be used as the first choice of antibacterial medicine to treat lower respiratory tract infections caused by a certain type of bacterial called *Streptococcus pneumoniae*.

Ciprofloxacin tablets are also used in children younger than 18 years of age to treat complicated urinary tract and kidney infections or who may have breathed in anthrax germs, have plague or have been exposed to plague germs.

Children younger than 18 years of age have a higher chance of getting bone, joint, or tendon (musculoskeletal) problems such as pain or swelling while taking ciprofloxacin tablets. Ciprofloxacin tablets should not be used as the first choice of antibacterial medicine in children under 18 years of age.

Who should not take ciprofloxacin tablets?

Do not take ciprofloxacin tablets if you:

have ever had a severe allergic reaction to an antibacterial medicine known as a fluoroquinolone, or are allergic to ciprofloxacin hydrochloride or any of the ingredients in ciprofloxacin tablets. See the end of this Medication Guide for a complete list of ingredients in ciprofloxacin tablets.

also take a medicine called tizanidine (Zanaflex®).

Ask your healthcare provider if you are not sure.

What should I tell my healthcare provider before taking ciprofloxacin tablets?

Before you take ciprofloxacin tablets, tell your healthcare provider about all your medical conditions, including if you:

have tendon problems; ciprofloxacin tablets should not be used in patients who have a history of tendon problems.

have a disease that causes muscle weakness (myasthenia gravis); ciprofloxacin tablets should not be used in patients who have a known history of myasthenia gravis

have liver problems

have central nervous system problems (such as epilepsy).

have nerve problems. Ciprofloxacin tablets should not be used in patients who have a history of a nerve problem called peripheral neuropathy have or anyone in your family has an irregular heartbeat, or heart attack, especially a condition called "QT prolongation".

have low blood potassium (hypokalemia) or low magnesium (hypomagnesemia).

have or have had seizures.

have kidney problems. You may need a lower dose of ciprofloxacin tablets if your kidneys do not work well.

have diabetes or problems with low blood sugar (hypoglycemia).

have joint problems including rheumatoid arthritis (RA)

have trouble swallowing pills.

are pregnant or plan to become pregnant. It is not known if ciprofloxacin tablets will harm your unborn baby.

are breastfeeding or plan to breastfeed. Ciprofloxacin passes into your breast milk.

You should not breastfeed during treatment with ciprofloxacin tablets and for 2 days after taking your last dose of ciprofloxacin tablets. You may pump your breast milk and throw it away during treatment with ciprofloxacin tablets and for 2 days after taking your last dose of ciprofloxacin tablets.

If you are taking ciprofloxacin for inhalation anthrax, you and your healthcare provider should decide whether you can continue breastfeeding while taking ciprofloxacin tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Ciprofloxacin tablets and other medicines can affect each other causing side effects.

Especially tell your healthcare provider if you take:

a steroid medicine.

an anti-psychotic medicine.

a tricyclic antidepressant.

a water pill (diuretic).

theophylline (such as Theo-24®, Elixophyllin®, Theochron®, Uniphyl®, Theolair®).

a medicine to control your heart rate or rhythm (antiarrhythmics)

an oral anti-diabetes medicine.

phenytoin (Fosphenytoin Sodium®, Cerebyx®, Dilantin-125®, Dilantin®, Extended Phenytoin Sodium®, Prompt Phenytoin Sodium®, Phenytek®).

cyclosporine (Gengraf®, Neoral®, Sandimmune®, Sangcya®).

a blood thinner (such as warfarin, Coumadin®, Jantoven®).

methotrexate (Trexall®).

ropinirole (Requip®).

clozapine (Clozaril®, Fazaclo® ODT®).

a Non-Steroidal Anti-Inflammatory Drug (NSAID). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take ciprofloxacin tablets or other fluoroquinolones may increase your risk of central nervous system effects and seizures.

sildenafil (Viagra®, Revatio®).

duloxetine.

products that contain caffeine.

probenecid (Probalan®, Col-probenecid®).

Certain medicines may keep ciprofloxacin tablets from working correctly. Take ciprofloxacin tablets either 2 hours before or 6 hours after taking these medicines, vitamins, or supplements:

an antacid, multivitamin, or other medicine or supplements that has magnesium, calcium, aluminum, iron, or zinc.

sucralfate (Carafate®).

didanosine (Videx®, Videx EC®).

Ask your healthcare provider for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ciprofloxacin tablets?

Take ciprofloxacin tablets exactly as your healthcare provider tells you to take them.

Your healthcare provider will tell you how much ciprofloxacin to take and when to take it.

Take ciprofloxacin tablets in the morning and evening at about the same time each day. Swallow the tablet whole. Do not split, crush or chew the tablet. Tell your healthcare provider if you cannot

swallow the tablet whole.

Ciprofloxacin tablets can be taken with or without food.

If you miss a dose of ciprofloxacin tablets and it is:

6 hours or more until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.

less than 6 hours until your next scheduled dose, do not take the missed dose. Take the next dose at your regular time.

Do not take 2 doses of ciprofloxacin tablets at one time to make up for a missed dose. If you are not sure about when to take ciprofloxacin tablets after a missed dose, ask your doctor or pharmacist.

Ciprofloxacin tablets should not be taken with dairy products (like milk or yogurt) or calcium-fortified juices alone, but may be taken with a meal that contains these products.

Drink plenty of fluids while taking ciprofloxacin tablets.

Do not skip any doses of ciprofloxacin tablets, or stop taking them, even if you begin to feel better, until you finish your prescribed treatment unless:

you have tendon problems. See “What is the most important information I should know about ciprofloxacin tablets?”

you have nerve problems. See “What is the most important information I should know about ciprofloxacin tablets?”

you have central nervous system problems. See “What is the most important information I should know about ciprofloxacin tablets?”

you have a serious allergic reaction. See “What are the possible side effects of ciprofloxacin tablets?”

your healthcare provider tells you to stop taking ciprofloxacin tablets.

Taking all of your ciprofloxacin tablet doses will help make sure that all of the bacteria are killed.

Taking all of your ciprofloxacin tablet doses will help lower the chance that the bacteria will become resistant to ciprofloxacin tablets. If you become resistant to ciprofloxacin tablets, ciprofloxacin tablets and other antibacterial medicines may not work for you in the future.

If you take too much ciprofloxacin, call your healthcare provider or get medical help right away.

What should I avoid while taking ciprofloxacin tablets?

Ciprofloxacin tablets can make you feel dizzy and lightheaded. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how ciprofloxacin tablets affect you.

Avoid sunlamps, tanning beds, and try to limit your time in the sun. Ciprofloxacin tablets can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You could get a severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while you take ciprofloxacin tablets, call your healthcare provider right away. You should use a sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight.

What are the possible side effects of ciprofloxacin tablets?

Ciprofloxacin tablets may cause serious side effects, including:

See “What is the most important information I should know about ciprofloxacin tablets?”

Serious allergic reactions. Serious allergic reactions, including death, can happen in people taking fluoroquinolones, including ciprofloxacin tablets, even after only 1 dose. Stop taking ciprofloxacin tablets and get emergency medical help right away if you get any of the following symptoms of a severe allergic reaction:

hives

trouble breathing or swallowing

swelling of the lips, tongue, face

throat tightness, hoarseness

rapid heartbeat

faint
skin rash

Skin rash may happen in people taking ciprofloxacin tablets even after only 1 dose. Stop taking ciprofloxacin tablets at the first sign of a skin rash and call your healthcare provider. Skin rash may be a sign of a more serious reaction to ciprofloxacin tablets.

Liver damage (hepatotoxicity). Hepatotoxicity can happen in people who take ciprofloxacin tablets. Call your healthcare provider right away if you have unexplained symptoms such as:

nausea or vomiting
stomach pain
fever
weakness
abdominal pain or tenderness
itching
unusual tiredness
loss of appetite
light colored bowel movements
dark colored urine
yellowing of the skin and whites of your eyes

Stop taking ciprofloxacin tablets and tell your healthcare provider right away if you have yellowing of your skin or white part of your eyes, or if you have dark urine. These can be signs of a serious reaction to ciprofloxacin tablets (a liver problem).

Aortic aneurysm and dissection. Tell your healthcare provider if you have ever been told that you have an aortic aneurysm, a swelling of the large artery that carries blood from the heart to the body. Get emergency medical help right away if you have sudden chest, stomach, or back pain.

Intestine infection (*Clostridioides difficile* - associated diarrhea). *Clostridioides difficile*-associated diarrhea (CDAD) can happen with many antibacterial medicines, including ciprofloxacin tablets. Call your healthcare provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody stools. You may have stomach cramps and a fever. CDAD can happen 2 or more months after you have finished your antibacterial medicine.

Serious heart rhythm changes (QT prolongation and torsade de pointes). Tell your healthcare provider right away if you have a change in your heart beat (a fast or irregular heartbeat), or if you faint.

Ciprofloxacin tablets may cause a rare heart problem known as prolongation of the QT interval. This condition can cause an abnormal heartbeat and can be very dangerous. The chances of this event are higher in people:

who are elderly.
with a family history of prolonged QT interval.
with low blood potassium (hypokalemia) or low magnesium (hypomagnesemia).
who take certain medicines to control heart rhythm (antiarrhythmics).

Joint Problems. Increased chance of problems with joints and tissues around joints in children under 18 years old can happen. Tell your child's healthcare provider if your child has any joint problems during or after treatment with ciprofloxacin tablets.

Sensitivity to sunlight (photosensitivity). See "What should I avoid while taking ciprofloxacin tablets?"
Changes in blood sugar. People who take ciprofloxacin and other fluoroquinolone medicines with oral anti-diabetes medicines or with insulin can get low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia). Follow your healthcare provider's instructions for how often to check your blood sugar. If you have diabetes and you get low blood sugar while taking ciprofloxacin, stop taking ciprofloxacin and call your healthcare provider right away. Your antibiotic medicine may need to be changed.

The most common side effects of ciprofloxacin tablets include:

nausea
diarrhea
changes in liver function tests
vomiting
rash

Tell your healthcare provider about any side effect that bothers you, or that does not go away.

These are not all the possible side effects of ciprofloxacin tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ciprofloxacin tablets?

Store at room temperature between 20° to 25°C (68° to 77°F).

Keep ciprofloxacin tablets and all medicines out of the reach of children.

General Information about the safe and effective use of ciprofloxacin tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ciprofloxacin tablets for a condition for which it is not prescribed. Do not give ciprofloxacin tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about ciprofloxacin tablets. If you would like more information about ciprofloxacin tablets, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ciprofloxacin tablets that is written for healthcare professionals.

What are the ingredients in ciprofloxacin tablets?

Active ingredient: ciprofloxacin hydrochloride

Inactive ingredients: colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, and titanium dioxide.

For more information call Northstar Rx LLC at 1-800-206-7821.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Dosage and Administration Section

2 DOSAGE AND ADMINISTRATION

Ciprofloxacin tablets should be administered orally as described in the appropriate Dosage Guidelines tables.

2.1 Dosage in Adults

The determination of dosage and duration for any particular patient must take into consideration the severity and nature of the infection, the susceptibility of the causative microorganism, the integrity of the patient's host-defense mechanisms, and the status of renal and hepatic function. Ciprofloxacin tablets may be administered to adult patients when clinically indicated at the discretion of the physician.

Table 1: Adult Dosage Guidelines

1. Generally ciprofloxacin should be continued for at least 2 days after the signs and symptoms of infection have disappeared, except for inhalational anthrax (post-exposure).
2. Used in conjunction with metronidazole.
3. Begin drug administration as soon as possible after suspected or confirmed exposure.

Infection

Dose

Frequency

Usual Durations¹

Skin and Skin Structure

500 to 750 mg

every 12 hours

7 to 14 days

Bone and Joint

500 to 750 mg

every 12 hours

4 to 8 weeks

Complicated Intra-Abdominal²

500 mg

every 12 hours

7 to 14 days

Infectious Diarrhea

500 mg

every 12 hours

5 to 7 days

Typhoid Fever

500 mg

every 12 hours

10 days

Uncomplicated Urethral and Cervical Gonococcal Infections

250 mg

single dose

single dose

Inhalational anthrax (post-exposure)³

500 mg

every 12 hours

60 days

Plague³

500 to 750 mg

every 12 hours

14 days

Chronic Bacterial Prostatitis

500 mg
every 12 hours
28 days
Lower Respiratory Tract Infections
500 to 750 mg
every 12 hours
7 to 14 days
Urinary Tract Infections
250 to 500 mg
every 12 hours
7 to 14 days
Acute Uncomplicated Cystitis
250 mg
every 12 hours
3 days
Acute Sinusitis
500 mg
every 12 hours
10 days

Conversion of IV to Oral Dosing in Adults

Patients whose therapy is started with ciprofloxacin IV may be switched to ciprofloxacin tablets when clinically indicated at the discretion of the physician (Table 2) [see CLINICAL PHARMACOLOGY (12.3)].

Table 2: Equivalent AUC Dosing Regimens

Ciprofloxacin Oral Dosage
Equivalent Ciprofloxacin IV Dosage
250 mg Tablet every 12 hours
200 mg intravenous every 12 hours
500 mg Tablet every 12 hours
400 mg intravenous every 12 hours
750 mg Tablet every 12 hours
400 mg intravenous every 8 hours

2.2 Dosage in Pediatric Patients

Dosing and initial route of therapy (that is, IV or oral) for cUTI or pyelonephritis should be determined by the severity of the infection. Ciprofloxacin tablets should be administered as described in Table 3.

Table 3: Pediatric Dosage Guidelines

1. The total duration of therapy for cUTI and pyelonephritis in the clinical trial was determined by the physician. The mean duration of treatment was 11 days (range 10 to 21 days).
2. Begin drug administration as soon as possible after suspected or confirmed exposure.
3. Begin drug administration as soon as possible after suspected or confirmed exposure to *Y. pestis*.

Infection

Dose

Frequency

Total Duration

Complicated Urinary Tract or Pyelonephritis (patients from 1 to 17 years of age)
10 mg/kg to 20 mg/kg (maximum 750 mg per dose; not to be exceeded even in patients weighing more than 51 kg).
Every 12 hours
10 to 21 days¹
Inhalational Anthrax (Post-Exposure)²

15 mg/kg (maximum 500 mg per dose)

Every 12 hours

60 days

Plague^{2,3}

15 mg/kg (maximum 500 mg per dose)

Every 8 to 12 hours

14 days

2.3 Dosage Modifications in Patients with Renal Impairment

Ciprofloxacin is eliminated primarily by renal excretion; however, the drug is also metabolized and partially cleared through the biliary system of the liver and through the intestine. These alternative pathways of drug elimination appear to compensate for the reduced renal excretion in patients with renal impairment. Nonetheless, some modification of dosage is recommended, particularly for patients with severe renal dysfunction. Dosage guidelines for use in patients with renal impairment are shown in Table 4.

Table 4: Recommended Starting and Maintenance Doses for Adult Patients with Impaired Renal Function
Creatinine Clearance (mL/min)

Dose

> 50

See Usual Dosage.

30 to 50

250 to 500 mg every 12 hours

5 to 29

250 to 500 mg every 18 hours

Patients on hemodialysis or Peritoneal dialysis

250 to 500 mg every 24 hours (after dialysis)

When only the serum creatinine concentration is known, the following formulas may be used to estimate creatinine clearance:

Men - Creatinine clearance (mL/min) = $\text{Weight (kg)} \times (140 - \text{age})$

$72 \times \text{serum creatinine (mg/dL)}$

Women - 0.85 x the value calculated for men.

The serum creatinine should represent a steady state of renal function.

In patients with severe infections and severe renal impairment, a unit dose of 750 mg may be administered at the intervals noted above. Patients should be carefully monitored.

Pediatric patients with moderate to severe renal insufficiency were excluded from the clinical trial of cUTI and pyelonephritis. No information is available on dosing adjustments necessary for pediatric patients with moderate to severe renal insufficiency (that is, creatinine clearance of < 50 mL/min/1.73 m²).

2.4 Important Administration Instructions

With Multivalent Cations

Administer ciprofloxacin tablets at least 2 hours before or 6 hours after magnesium/aluminum antacids; polymeric phosphate binders (for example, sevelamer, lanthanum carbonate) or sucralfate; Videx® (didanosine) chewable/buffered tablets or pediatric powder for oral solution; other highly buffered drugs; or other products containing calcium, iron or zinc.

With Dairy Products

Concomitant administration of ciprofloxacin tablets with dairy products (like milk or yogurt) or calcium-fortified juices alone should be avoided since decreased absorption is possible; however,

ciprofloxacin tablets may be taken with a meal that contains these products.

Hydration of Patients Receiving Ciprofloxacin Tablets

Assure adequate hydration of patients receiving ciprofloxacin tablets to prevent the formation of highly concentrated urine. Crystalluria has been reported with quinolones.

Instruct the patient of the appropriate ciprofloxacin tablets administration [see PATIENT COUNSELING INFORMATION (17)].

Missed Doses

If a dose is missed, it should be taken anytime but not later than 6 hours prior to the next scheduled dose. If less than 6 hours remain before the next dose, the missed dose should not be taken and treatment should be continued as prescribed with the next scheduled dose. Double doses should not be taken to compensate for a missed dose.

Indications and Usage Section

1 INDICATIONS AND USAGE

1.1 Skin and Skin Structure Infections

Ciprofloxacin tablets are indicated in adult patients for treatment of skin and skin structure infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia stuartii*, *Morganella morganii*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, methicillin-susceptible *Staphylococcus aureus*, methicillin-susceptible *Staphylococcus epidermidis*, or *Streptococcus pyogenes*.

1.2 Bone and Joint Infections

Ciprofloxacin tablets are indicated in adult patients for treatment of bone and joint infections caused by *Enterobacter cloacae*, *Serratia marcescens*, or *Pseudomonas aeruginosa*.

1.3 Complicated Intra-Abdominal Infections

Ciprofloxacin tablets are indicated in adult patients for treatment of complicated intra-abdominal infections (used in combination with metronidazole) caused by *Escherichia coli*, *Pseudomonas aeruginosa*, *Proteus mirabilis*, *Klebsiella pneumoniae*, or *Bacteroides fragilis*.

1.4 Infectious Diarrhea

Ciprofloxacin tablets are indicated in adult patients for treatment of infectious diarrhea caused by *Escherichia coli* (enterotoxigenic isolates), *Campylobacter jejuni*, *Shigella boydii*†, *Shigella dysenteriae*, *Shigella flexneri* or *Shigella sonnei*† when antibacterial therapy is indicated.

†Although treatment of infections due to this organism in this organ system demonstrated a clinically significant outcome, efficacy was studied in fewer than 10 patients.

1.5 Typhoid Fever (Enteric Fever)

Ciprofloxacin tablets are indicated in adult patients for treatment of typhoid fever (enteric fever) caused by *Salmonella typhi*. The efficacy of ciprofloxacin in the eradication of the chronic typhoid carrier state has not been demonstrated.

1.6 Uncomplicated Cervical and Urethral Gonorrhea

Ciprofloxacin tablets are indicated in adult patients for treatment of uncomplicated cervical and urethral gonorrhea due to *Neisseria gonorrhoeae* [see WARNINGS AND PRECAUTIONS (5.17)].

1.7 Inhalational Anthrax (Post-Exposure)

Ciprofloxacin tablets are indicated in adults and pediatric patients from birth to 17 years of age for inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following

exposure to aerosolized *Bacillus anthracis*.

Ciprofloxacin serum concentrations achieved in humans served as a surrogate endpoint reasonably likely to predict clinical benefit and provided the initial basis for approval of this indication.¹ Supportive clinical information for ciprofloxacin for anthrax post-exposure prophylaxis was obtained during the anthrax bioterror attacks of October 2001 [see CLINICAL STUDIES (14.2)].

1.8 Plague

Ciprofloxacin tablets are indicated for treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (*Y. pestis*) and prophylaxis for plague in adults and pediatric patients from birth to 17 years of age. Efficacy studies of ciprofloxacin could not be conducted in humans with plague for feasibility reasons. Therefore this indication is based on an efficacy study conducted in animals only [see CLINICAL STUDIES (14.3)].

1.9 Chronic Bacterial Prostatitis

Ciprofloxacin tablets are indicated in adult patients for treatment of chronic bacterial prostatitis caused by *Escherichia coli* or *Proteus mirabilis*.

1.10 Lower Respiratory Tract Infections

Ciprofloxacin tablets are indicated in adult patients for treatment of lower respiratory tract infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, or *Streptococcus pneumoniae*.

Ciprofloxacin tablets are not a drug of first choice in the treatment of presumed or confirmed pneumonia secondary to *Streptococcus pneumoniae*.

Ciprofloxacin tablets are indicated for the treatment of acute exacerbations of chronic bronchitis (AECB) caused by *Moraxella catarrhalis*.

Because fluoroquinolones, including ciprofloxacin tablets, have been associated with serious adverse reactions [see WARNINGS AND PRECAUTIONS (5.1 to 5.16)] and for some patients AECB is self-limiting, reserve ciprofloxacin tablets for treatment of AECB in patients who have no alternative treatment options.

1.11 Urinary Tract Infections

Urinary Tract Infections in Adults

Ciprofloxacin tablets are indicated in adult patients for treatment of urinary tract infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Serratia marcescens*, *Proteus mirabilis*, *Providencia rettgeri*, *Morganella morganii*, *Citrobacter koseri*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, methicillin-susceptible *Staphylococcus epidermidis*, *Staphylococcus saprophyticus*, or *Enterococcus faecalis*.

Acute Uncomplicated Cystitis

Ciprofloxacin tablets are indicated in adult female patients for treatment of acute uncomplicated cystitis caused by *Escherichia coli* or *Staphylococcus saprophyticus*.

Because fluoroquinolones, including ciprofloxacin tablets, have been associated with serious adverse reactions [see WARNINGS AND PRECAUTIONS (5.1 to 5.16)] and for some patients acute uncomplicated cystitis is self-limiting, reserve ciprofloxacin tablets for treatment of acute uncomplicated cystitis in patients who have no alternative treatment options.

Complicated Urinary Tract Infection and Pyelonephritis in Pediatric Patients

Ciprofloxacin tablets are indicated in pediatric patients aged one to 17 years of age for treatment of complicated urinary tract infections (cUTI) and pyelonephritis due to *Escherichia coli* [see USE IN

SPECIFIC POPULATIONS (8.4)].

Although effective in clinical trials, ciprofloxacin tablets are not a drug of first choice in the pediatric population due to an increased incidence of adverse reactions compared to controls, including reactions related to joints and/or surrounding tissues. Ciprofloxacin tablets, like other fluoroquinolones, is associated with arthropathy and histopathological changes in weight-bearing joints of juvenile animals [see WARNINGS AND PRECAUTIONS (5.13), ADVERSE REACTIONS (6.1), USE IN SPECIFIC POPULATIONS (8.4) and NONCLINICAL TOXICOLOGY (13.2)].

1.12 Acute Sinusitis

Ciprofloxacin tablets are indicated in adult patients for treatment of acute sinusitis caused by *Haemophilus influenzae*, *Streptococcus pneumoniae*, or *Moraxella catarrhalis*.

Because fluoroquinolones, including ciprofloxacin tablets, have been associated with serious adverse reactions [see WARNINGS AND PRECAUTIONS (5.1 to 5.16)] and for some patients acute sinusitis is self-limiting, reserve ciprofloxacin tablets for treatment of acute sinusitis in patients who have no alternative treatment options.

1.13 Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ciprofloxacin tablets and other antibacterial drugs, ciprofloxacin tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

If anaerobic organisms are suspected of contributing to the infection, appropriate therapy should be administered. Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing infection and to determine their susceptibility to ciprofloxacin. Therapy with ciprofloxacin tablets may be initiated before results of these tests are known; once results become available appropriate therapy should be continued.

As with other drugs, some isolates of *Pseudomonas aeruginosa* may develop resistance fairly rapidly during treatment with ciprofloxacin. Culture and susceptibility testing performed periodically during therapy will provide information not only on the therapeutic effect of the antimicrobial agent but also on the possible emergence of bacterial resistance.

Principal Display Panel

Rx only

NDC 16714-652-02

**Ciprofloxacin
Tablets, USP**
500 mg

PHARMACIST: PLEASE DISPENSE WITH
MEDICATION GUIDE PROVIDED SEPARATELY.

100 Tablets

NORTHSTAR[®]

Each film-coated tablet contains:
582 mg of ciprofloxacin hydrochloride
monohydrate equivalent to 500 mg
ciprofloxacin USP.

Usual Dosage: See package insert for
Dosage and Administration.

Store at 20° to 25°C (68° to 77°F);
excursions permitted to 15° to 30°C (59° to
86°F) [see USP Controlled Room
Temperature].

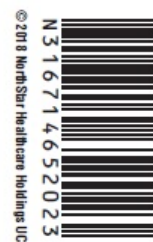
Medication Guides available at
www.northstarrxllc.com/products or call
1-800-206-7821.

Product of India

Manufactured for:
Northstar Rx LLC
Memphis, TN 38141.

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 090, India.

M.L.No.: 19/HD/AP/95/F/R
Revised: 06/2020



P1426442



* Over Printing Zone

Coding Area
(45 x 20 mm)
Dotted line not to be printed

CIPRO

ciprofloxacin hcl 500mg tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:80425-0095(NDC:16714-652)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CIPROFLOXACIN HYDROCHLORIDE (UNII: 4BA73M5E37) (CIPROFLOXACIN - UNII:5E8K9I0O4U)	CIPROFLOXACIN	500 mg

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	18 mm
Flavor		Imprint Code	C;94
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0095-2	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA077859	04/26/2007	
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Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0095)

Revised: 11/2020

Advanced Rx Pharmacy of Tennessee, LLC